

JAN 19 2010 NF

MICHAEL W. DOBBINS  
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

THE UNITED STATES OF AMERICA  
*ex rel.* FARID KARIMI; THE STATE  
OF ILLINOIS *ex rel.* FARID KARIMI,  
and FARID KARIMI, individually,

Plaintiffs,

v.

Dr. Reddy's Laboratories, Inc., and  
Dr. Reddy's Laboratories, Ltd.,

Defendants.

FILED UNDER SEAL

JURY TRIAL DEMANDED

COMPLAINT

10cv371

Judge James F. Holderman  
Magistrate Judge Jeffrey Cole

Plaintiffs complain and state as follows:

**I. NATURE OF THE ACTION**

1. This is an action to recover damages and civil penalties on behalf of the United States of America under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended ("the FCA"), and a related state false claims act, the Illinois Whistleblower Reward and Protection Act, 740 ILCS §§ 175/1 *et seq.* (Hereinafter, the FCA and the Illinois Whistleblower Reward and Protection Act will be referred to as the "FCAs." The United States and the State of Illinois are hereinafter referred to as the "Governments.").

2. The FCAs causes of action arise from false statements, records, and claims by Defendants Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's" or "Defendants") and/or their agents, and employees in violation of the FCAs. These violations involve false or fraudulent claims for payment or approval presented and/or false records

Defendants have made, used, or caused to be made or used, in order to get false or fraudulent claims paid or approved by the Governments.

3. These claims are based on Dr. Reddy's causing claims to be submitted to the Governments for generic prescription drugs that are not as high quality, strong, pure, or as stable as the brand name drug or as the generic drug it purports to be. Simply put, the Governments and the federal and state healthcare beneficiaries are not getting what they paid for.

## **II. PARTIES**

4. Relator, FARID KARIMI ("Karimi" or "Relator"), is a resident of Illinois and a licensed physician. Dr. Karimi obtained his medical degree from the University of Tehran Medical School. Dr. Karimi is a licensed psychiatrist in the States of Illinois.

5. Dr. Reddy's Laboratories, Ltd., is a global pharmaceutical company with is product line focused on India, the United States, Europe and Russia. Dr. Reddy's Laboratories, Ltd.'s wholly owned United States subsidiary is, Dr. Reddy's Laboratories, Inc., located at 200 Somerset Corporate Blvd., Building 11, 7th Floor, Bridgewater, New Jersey. Dr. Reddy's Laboratories, Ltd.'s United States representative office is located at, 3600 Arco Corporate Drive, Suite 310, Charlotte, North Carolina. Dr. Reddy's operates seven generic drug manufacturing plants worldwide, with six Federal Drug Administration ("FDA") inspected formulation plants in India and one in the United States.

## **III. JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

7. This Court has supplemental jurisdiction over the *qui tam* Relator's state law claims pursuant to 28 U.S.C. § 1367, as those claims are so related to the federal claims that they form part of the same case and controversy under Article III of the United States Constitution. This Court also has jurisdiction over the state law claims pursuant to 31 U.S.C. § 3732(b), as the state law claims arise from the same transactions and occurrences as the federal action.

8. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Defendants transact business in the United States. Defendants can be found in, resides in, and/or transact or have transacted business related to the allegations in this complaint within the Northern District of Illinois.

9. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. § 1391(b) and (c), as Defendants can be found in, resides in, and/or transacts business in the Northern District of Illinois.

10. This suit is not based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government General Accounting Office report, hearing, audit, or investigation, or from the news media.

11. To the extent that there has been a public disclosure, unknown to Relator, Relator is an original source under 31 U.S.C. § 3730(e)(4)(B), and 740 ILCS 175/4(e)(4)(B). Relator has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Governments before filing an action under this section which is based on the information.

12. Relator Karimi served on the Attorney General of the United States, the United States Attorney for the Northern District of Illinois, and the Illinois Attorney General,

substantially all material evidence and information he possess in accordance with the provisions of 31 U.S.C. §3730(b)(2), and 740 ILCS 175/4(b)(2).

#### **IV. THE FEDERAL FALSE CLAIMS ACT**

13. The False Claims Act provides, in pertinent part that: any person who - -

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

#### **V. THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT**

14. The Illinois Whistleblower Reward and Protection Act provides, in pertinent part:

- (a) Liability for certain acts. Any person who:
  - (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
  - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

\* \* \*

is liable to the State for a civil penalty of not less than \$ 5,500 and not more than \$ 11,000, plus 3 times the amount of damages which the State sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.

§ 740 ILCS 175/3

## **VI. THE MEDICARE AND MEDICAID PROGRAMS**

15. The Medicare program was enacted under Title XVIII of the Social Security Act, in 1965, to pay for certain healthcare services based primarily on age. 42 U.S.C. §§ 426, 226A.

16. The Department of Health and Human Services ("HHS") administers the Medicare Program, 42 U.S.C. §§ 1395 et seq., and the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq. The Center for Medicare and Medicaid Services ("CMS") is the agency of HHS that is directly responsible for the administration of the Medicare Program.

17. Medicaid is a program that provides medical assistance for individuals and families with low incomes. The Medicaid program became law in 1965 and is jointly funded by the states and the federal government.

18. Medicaid is administered by the Illinois Department of Healthcare and Family Services.

## **VII. THE DEFENDANT'S SCHEME TO DEFRAUD**

19. Defendants' scheme to defraud consists of manufacturing, selling, producing or distributing the generic version of Lamictal, a prescription drug used to prevent or control seizures (epilepsy) and to help prevent and stabilize the depression associated with people suffering bipolar disorder. GlaxoSmithKline manufactures Lamictal. Lamotrigine, the generic version at issue in this matter, is produced by Dr. Reddy's and is not as high quality, strong, pure or as stable as the brand name drug or as the Lamotrigine it purports to be. This weaker and thus defective drug, is being prescribed to federal and state health care program beneficiaries and claims are being submitted for its reimbursement to the Governments. Because the Lamotrigine being supplied by Dr. Reddy's is not as high quality, strong, pure or as stable as the brand name

drug, and as the generic drug it purports to be, claims submitted to the Governments for Dr. Reddy's Lamotrigine are false or fraudulent.

20. Lamictal is one of the top selling non-generic drugs in the United States, with annual sales of about \$2.2 billion. In 2008, annual sales for Lamotrigine, as manufactured by Dr. Reddy's and other generic drug makers, were about \$671 million.

21. On information and belief, Relator states that Dr. Reddy's defective Lamotrigine is being sold nationwide and that the defective Lamotrigine is being sold to federal and state healthcare program beneficiaries, including Medicare, Medicaid, TRICARE, CHAMPUS, Illinois Cares Rx, and other third party payor programs, as stated herein, from no later than April 2009 through the present.

**COUNT 1**  
**(Federal False Claims Act – Presentation of False Claims)**  
**(31 U.S.C. § 3729 (a)(1)(A))**

22. Relator repeats and realleges each and every allegation contained above as if fully set forth herein.

23. Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States.

24. By virtue of the false and fraudulent claims made by Defendants, the United States suffered damages and therefore is entitled to multiple damages under the Federal False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

**COUNT II**  
**(Federal False Claims Act – False Record or Statement)**  
**(31 U.S.C. § 3729 (a)(1)(B))**

25. Relator repeats and realleges each and every allegation contained above as if fully set forth herein.

26. Defendants knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim

27. By virtue of the false and fraudulent claims made by Defendants, the United States suffered damages and therefore is entitled to multiple damages under the Federal False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

**COUNT III**  
**(Illinois Whistleblower Reward and Protection Act – Presentation of False Claims)**  
**(740 ILCS 175/3(a)(1))**

28. Relator repeats and realleges each and every allegation contained above as if fully set forth herein.

29. Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the State of Illinois.

30. By virtue of the false and fraudulent claims made by Defendants, the State of Illinois suffered damages and therefore is entitled to multiple damages under the Illinois Whistleblower Reward and Protection Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

**COUNT IV**  
**(Illinois Whistleblower Reward and Protection Act – False Record or Statement)**  
**(740 ILCS 175/3(a)(2))**

31. Relator repeats and realleges each and every allegation contained above as if fully set forth herein.

32. Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

33. By virtue of the false and fraudulent claims made by Defendants, the State of Illinois suffered damages and therefore is entitled to multiple damages under the Illinois

Whistleblower Reward and Protection Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each violation.

WHEREFORE, Relator prays that the Court enter judgment against Defendants and in favor of the Governments and Relator as follows:

A. Order Defendants to cease and desist from violating the False Claims Acts as stated herein;

B. Award the Governments the maximum amount of damages they sustained as a result of Defendants' actions, as well as the maximum amount of civil penalties, as permitted, for each violation of the Governments' False Claims Acts.

C. Award Relator Karimi the maximum reward allowed pursuant to the *qui tam* provisions of the Governments' False Claims Act.

D. Award Relator Karimi all costs and expenses of this action, including Attorney's fees; and

E. Awarding the Governments and Relator Karimi all such relief as the Court deems just and proper.

**JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Relators hereby demands trial by jury.

By:

  
Attorney for Relator/Plaintiff

Dated: January 19, 2010

Michael C. Rosenblat  
Brian P. McLaughlin  
**ROSENBLAT & ASSOCIATES, LTD.**  
33 N. LaSalle, Suite 2900  
Chicago, IL 60602